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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,901	08/07/2001	Kanji Takada	P21010	2415

7055 7590 09/09/2004

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,901	TAKADA, KANJI	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *9 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed May 27, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-18 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention

The invention provides a formulation for gastric drug delivery wherein the formulation adheres to the selected site in the intestines.

(2) The state of the prior art

The formulations of the invention are patch or tape like formulations. However, the art does not teach tape or patch like formulations that are orally ingested and adhere to the intestines.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the oral formulation art is very high. Different types of formulations release and delivery the drugs to different portion of the digestive tract as well as different portion of the body (i.e., buccal patches, inhalation formulation, transdermal patches, suppositories, etc.). The pharmacokinetics of each drug also play a role in determining the most effective means to administer that particular drug.

(5) The breadth of the claims

The claims are very broad. The formulation contains an adhesion site-controlling layer, a drug adhesion layer and a protective layer wherein the site-controlling layer dissolves in the intestines and is an enteric polymer and may attach to the protective layer. The protective layer is not defined in any specifics other than to say that it can be a film or a capsule made of water-insoluble polymer or a wax.

(6) The amount of direction or guidance presented

The specification sets forth examples of formulation being placed in the duodenum of rats by surgical means but does not set forth examples of the formulation being orally administered where the formulation would be subject to the entire digestive tract, including the mouth and stomach. There is no evidence that once orally administered the formulation actually reaches its target of a selected site in the intestines. There is no showing that the formulation passes through the stomach after oral administration and actually adheres to the intestines as is required by the instant claims.

As stated above, the state of the art is not helpful in determining the ability of the formulation to be orally administered and actually reach the intestines target and adhere to that target.

(7) The presence or absence of working examples

As stated above, the specification does teach that when surgically administered directly to the duodenum some of the formulations attach to the intestines but the specification is replete with examples of orally administering the formulation and formulation adhering to the intestines as is required by the instant claims.

(8) The quantity of experimentation necessary

Since the significance of the formulation reaching the intestines after oral administration cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine that the formulation actually reaches the intestines

after oral administration and does not adhere to another portion of the digestive tract prior to reaching the intestines.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-18 and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the formulation contains an adhesion site-controlling layer *for attaching the formulation to a selected site in the intestines*. The claim further recites that the drug-carrying layer contains an adhesive *to attach the drug-containing layer to the selected site in the intestines.* It is unclear to the Examiner what applicants intend to convey by this recitation. Do both layers attach to the intestines? Are they layers the same material? Are there two layers that are identical in the formulation? Clarification and/or amendment are suggested.

Claim 8 recites that the protective layer of the formulation is a film or a capsule made of a water-insoluble polymer or a wax. It is unclear whether both the film and the capsule are made of a water-insoluble polymer or just the capsule. In addition, it is unclear whether the capsule and/or film is made of water-insoluble polymer or a wax or if the protective layer can simply be a wax. Clarification and/or amendment are suggested.

Response to Arguments

Applicant's arguments with respect to claims 1-8, 10-18 and 20-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Due to the new grounds for rejection, this action is deemed non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600